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510(k) SUMMARY

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Device: VACUTAINER® Brand PLUS (plastic) Serum and SST® Serum Separator Tubes ("Full Draw" Tubes Only)

Classification 75JKA - Tubes, Vials, Systems, Serum Separators, Blood Collection

Predicate Device: VACUTAINER® Brand PLUS Serum and SST® Serum Separator Tubes (All Tube Volumes)

Intended Use: An evacuated tube which provides a means of collecting, transporting, separating and processing venous blood in a closed system. Blood collected in these tubes is primarily used for clinical laboratory chemistry assays using patient serum but may be used for other serum specimens as determined by the laboratory.

Proposed Modification: Reduction in the amount of the silicone tube coating.

Becton Dickinson VACUTAINER Systems has determined that the reduction in the amount of silicone surfactant in the "full draw" tubes will not impact the safety or effectiveness of the product for its intended use. Testing has shown that the clinical performance of the proposed tubes is equivalent to the current plastic tubes.

No new claims will be made for either the VACUTAINER® Brand PLUS Serum or PLUS SST® Serum Separator Tubes.

Synopsis of Test Methods and Results

- Breakage reduction is demonstrated in a study consisting of drop testing and centrifugation testing.

- Waste disposal improvement is demonstrated in a study of the by products of incineration for the components separately and the product as a whole.
- Reduced blood exposure is demonstrated in a study comparing VACUTAINER® Brand Tubes with the HEMOGARD™ closure to both VACUTAINER® Brand Tubes with the conventional rubber stopper and competitive tubes.
- Equivalent clinical performance to the current VACUTAINER® Brand Tubes was demonstrated in a study which compared the current VACUTAINER® Brand PLUS SST® Serum Separator Tube to the proposed VACUTAINER® Brand PLUS SST® Serum Separator Tube for the following analytes: albumin, alkaline phosphatase, alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin (initial time only), blood urea nitrogen (BUN), calcium, chloride, cholesterol, creatinine, glucose, gamma-glutamyl transferase (GGT), iron, phosphorus, potassium, sodium, protein, triglycerides, and uric acid. A difference in lactate dehydrogenase (LD) levels was noted. The performance characteristics of the gel barrier and the presence of fibrin, red cells and hemolysis were assessed visually. The partial draw evaluation tubes exhibited a film of red blood cells on the tube wall above the barrier; therefore, these tubes will not be modified. Note: All 13 X 100 size tubes used in clinical studies were partial draw tubes.

The results demonstrated equivalent functional performance.

- Minimization of the possibility of obtaining elevated levels of vitamin B₁₂ and folate obtained when these Tubes are used to collect samples to be tested on the CIBA Corning ACS:180® Analyzer was demonstrated in a study comparing the current glass VACUTAINER® Brand Serum Tube without silicone to the proposed VACUTAINER® Brand SST® Serum Separator Tube. The glass VACUTAINER® Brand Serum Tube was chosen as the control because this tube has no coatings. The study was performed in collaboration with CIBA Corning Diagnostics. NOTE: This report is proprietary and confidential and is the property of CIBA Corning Diagnostics and Becton Dickinson VACUTAINER Systems.

The results demonstrated a minimization of the interference.